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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,833	09/19/2003	Andrew H. Segal	11111/2003D	6845

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,833	SEGAL ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-13 are pending. Claim 4 is withdrawn for being directed to a non elected invention. Claims 1-3 and 5-13 are under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo.[1]

In response to the rejection, Applicant argues that Hoo does not anticipate the claimed invention because Hoo does not teach a composition comprising fusion polypeptide that is not bounded to a cell.

Applicant's arguments have been considered, however, it is not found persuasive. Contrary to Applicant's assertion, Hoo does teach a composition comprising fusion polypeptide that is both bounded and not bounded to a cell. The Office directs Applicant's attention to Example II of Hoo. At the cited example, Hoo administered unwashed cells expressing the composition. Hoo did not wash these cells to eliminate from the composition wherein the fusion polypeptide is not bounded to a cell. Thus, Hoo inherently teaches both bounded and unbounded compositions.

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[1] Hoo, W., U.S. Patent No. 5891432, published April 06, 1999.

Moreover, it is found that the procedure used by Hoo to administer both bounded and unbounded compositions is the same as Applicant. Per Applicant's disclosure, Applicant teaches that the administration of unwashed cells expressing the bounded compositions also includes unbounded compositions. See pages 176-178 of Applicant's disclosure. It remains that Hoo teaches the claimed invention. In the instant case, it is clearly established by the Office that the claimed invention is anticipated by the cited prior art, Hoo

The claims are directed to a composition comprising an antigen and a fusion polypeptide comprising i) a first amino acid sequence that can bind to a carbohydrate and ii) a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein the antigen and the fusion polypeptide are bounded and unbounded together. Claim 2, which depends on claim 1, limits the second amino acid sequence to a ligand for a cytokine receptor, which is limited to GM-CSF by claim 3. Claim 5, which depends on claim 1, requires the antigen to be a tumor cell, a bacterial cell, a fungal cell, a cell of a parasite, a mammalian cell or an insect cell. Claim 6, which depends on claim 5, requires the antigen to be a pathogenic cell or virus. Claim 7, which depends on claim 5, requires the antigen to be an attenuated cell or virus. Claim 8, which depends on claim 1, requires the antigen to be a cell that is unable to divide. Claim 9, which depends on claim 1, requires the leukocyte to be an antigen presenting cell, which is specified as a professional antigen presenting cell by claim 10 and dendritic cell by claim 11. Claim 13, which depends on claim 1, requires that that the

first amino acid sequence comprises a carbohydrate-binding domain of a naturally occurring lectin.

Hoo teaches a composition. [Claims 13-24, in particular.] The composition of Hoo comprises an antigen and a fusion polypeptide. [Claims 1-12, in particular.] In the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together. [Claim 1 and claim 12, in particular.] The antigen that Hoo teaches includes a virus, a bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, pathogenic and attenuated antigens, and a cell that is substantially unable to divide. [Lines 35-45, column 10, and columns 9-18, in particular.]

The first amino acid sequence in the fusion polypeptide of Hoo comprises the sequence to a membrane attachment domain, a cell-surface binding moiety. The second amino acid sequence in the fusion polypeptide of Hoo comprises the sequence of a ligand for a cell surface polypeptide of a leukocyte. Specifically, the ligand for a cell surface polypeptide of a leukocyte is a ligand for a cytokine receptor. In particular, the ligand for a cytokine receptor that Hoo teaches is GM-CSF. [Example I, column 22, in particular.] The ligand for a cell surface polypeptide used by Hoo is a ligand for a ligand for a cell surface polypeptide of a leukocyte, wherein the leukocyte is dendritic cells, which is a professional antigen presenting cell. [Columns 1-2, in particular.] In the instant case, the composition of Hoo is the same as the claimed invention. Therefore, the claimed invention is anticipated by Hoo.

In response to the rejection, Applicant argues that Hoo does not anticipate the claimed invention because Hoo does not teach a fusion polypeptide that is not bound to an antigen bearing target.

Applicant's argument has been considered, however, it is not found persuasive. As provided above, Hoo teaches a composition comprising an antigen bearing target and a fusion polypeptide. [Claim 1, in particular.] The antigen bearing target of Hoo includes a virus, a bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, pathogenic and attenuated antigens, and a cell that is substantially unable to divide. [Lines 35-45, column 10, and columns 9-18, in particular.] Hoo further teaches that the antigen bearing target can be fused, bound, to the fusion polypeptide. [Claim 12, in particular.] In the instant case, Hoo teaches both bound and unbounding of antigen bearing targets to the fusion polypeptide. Thus, contrary to Applicant's assertion, Hoo anticipates the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo, as applied to claim 1 above, in view of Stray et al.,[2] as evidenced by Rott et al.[3]

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[2] Stray et al. Influenza virus infection of desialyted cells. Glycobiology, 2000, Vol. 10, No. 7, 649-658.
[3] Rott et al. Influenza A virus hemagglutinin is a B cell-superstimulatory lectin. Med. Microbiol Immunol., 1996, 184-193.

In response to the rejection, Applicant repeated the argument summarized by the Office at paragraph no. 3 of this office action. The argument is not found persuasive for the reason(s) set forth at paragraph no. 3 of the instant office action.

Claim 12, which depends on claim 1, requires the first amino acid sequence to bind to a sialic acid on a glycoprotein.

The significance of Hoo, as applied to claim 1, is provided above. As noted above, the first amino acid sequence in the fusion polypeptide of Hoo comprises the sequence to a membrane attachment domain, a cell-surface binding moiety, from cell surface receptors. The first amino acid sequence of Hoo does not bind to a sialic acid on a glycoprotein. However, Hoo also suggests the use of other membrane attachment domains, a cell surface binding moiety, from cell surface receptors. [Lines 20-45, column 7, in particular.] At the time the invention was made, Stray et al. teaches a cell surface receptor. The cell surface receptor of Stray et al. is hemagglutinin. Stray et al. discloses that hemagglutinin has a membrane attachment domain, a cell surface binding moiety. The membrane attachment domain of hemagglutinin binds to sialic acid. And Rott et al. evidences that influenza hemagglutinin is a naturally occurring lectin.

In the instant case, at the time the invention was made, Hoo suggests the use of other membrane attachment domains and Stray et al. teaches that hemagglutinin, which has a membrane attachment domain that binds to sialic acid. Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was

made, to use the membrane attachment domain of hemagglutinin as suitable alternative to the membrane attachment domain taught by Hoo. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to produce a composition comprising a membrane bound cytokine (GM-CSF). One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of known suitable alternatives is routine practiced in the art.

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./
Primary Examiner, Art Unit 1648